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09.703.809	10/30/2000	Jeff L. DeJong	119941-1083	3391

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EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 07/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/703,809

Applicant(s)

DEJONG, JEFF L.

Examiner

Richard G Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 06 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 86-107 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 86-107 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-949)
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Examination (PTO-900)

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DETAILED ACTION

Applicants amendments canceling claim 69, Paper No. 12, 5/6/2003, and canceling claims 2, 33, 34, 68 and 71-85, and entering new claims 86-107, Paper No. 11, 2/22/2003, is acknowledged. Claims 86-107 are at issue and are present for examination. Claims 1-22 are still at issue and are present for examination.

Applicants' arguments filed on 2/22/2003, Paper No. 11, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Specification

The disclosure is objected to because of the following informalities:

As discussed in the previous office action, with respect to the claims and reference to specific sequence identifiers, the specification sometimes recites "SEQ ID NO.:" (i.e. page 44, lines 8 and 10) and sometimes recites "SEQ ID NO." (i.e. page 13, lines 7 and 9), "SEQ ID NO" (i.e. page 13, line 13). It is suggested that applicants maintain consistency throughout the application.

Throughout the specification "...transcriptional factor..." is recited numerous times (i.e. page 5, lines 21, 28, page 11, line 6, etc...) It is believed that this should be

specification and thus the objections are maintained.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 86-107 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 86 (87-91 dependent on), 92 (93-96 dependent on), 97 (98-102 dependent on), 103 (104-107 dependent on) are indefinite in the recitations "TFIIA α / β -like factor protein" and "Stoned TFIIA α / β -like factor protein" as the specification fails to teach which identifying characteristics distinguish an "TFIIA α / β -like factor protein" or a recitations "TFIIA α / β -like factor protein" from other proteins, which are distinct in sequence from SEQ ID NOs: 2 or 4. Thus it is unclear what characteristics of a protein distinguish it such that it may be considered to be within this class. It is noted that this is a similar rejection as that made previously for claims 71 (72-78 dependent on) and 79 (80-85 dependent on) and the recitation "ALF protein". In response to the previous referred to rejection applicants amended claims deleting the recitation.

Claim 93 (94-96 dependent on) is indefinite in that it is drawn to a fusion protein previously been cancelled was drawn to a DNA segment. For the purpose of compact

prosecution, claim 93 is interpreted as being drawn to a fusion protein comprising a portion of the TFIIA α / β -like factor protein of claim 92.

Claim 104 (105-107 dependent on) is indefinite in that it is drawn to a fusion protein comprising a portion of the Stoned TFIIA α / β -like factor protein of claim 18. Claim 18 which has previously been cancelled was drawn to a nucleic acid. For the purpose of compact prosecution, claim 104 is interpreted as being drawn to a fusion protein comprising a portion of the TFIIA α / β -like factor protein of claim 103.

Claims 92 (93-96 dependent on) and 103 (104-107 dependent on) are further indefinite in the recitation "...substantially homologous ...". It is unclear as to what the metes and bounds of the genus of those nucleic acid sequences that are considered by applicants to be "substantially homologous" to the recited SEQ ID NO. Outside of those which that protein encoded by SEQ ID NOs 1 or 3, there is nothing to suggest that other proteins would not also be included within the scope of this term and in the art what is considered substantially homologous varies widely depending on the individual situation as well as the person making the determination. As such it is unclear how homologous to the sequence of a gene encoding SEQ ID NOs: 1 or 3, a sequence must be to be included within the scope of these claims. It is noted that this is a similar rejection as that made previously for claims 71 (72-78 dependent on) and 79 (80-85 dependent on) and the recitation "...substantially homologous ...". In response to the same rejection to previous claims 71 (72-78 dependent on) and 79 (80-85 dependent

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claims remove the referred to language (Paper No. 11, page 4, last line through page 5, first two lines, 2/22/2003), however this does not in fact seem to be the case.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 86-88, 90-99 and 101-107 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 86-88, 90 and 91 are drawn to an isolated TFIIA α / β -like factor protein, wherein the protein comprises an amino acid sequence having greater than 90%, 95% or 98% amino acid sequence identity to SEQ ID NOs: 2 (claims 86-88, 90 and 91).

Claims 92-96 are drawn to an isolated TFIIA α / β -like factor protein encoded by a polynucleotide comprising a nucleic acid sequence substantially homologous to the coding strand of the gene sequence set forth in SEQ ID NO. 1 and fusion proteins comprising said protein. Claims 97-99 and 101-107 are drawn to an isolated Stoned TFIIA α / β -like factor protein encoded by a polynucleotide comprising a nucleic acid

in SEQ ID NO. 1 or 3 and fusion proteins comprising said protein.

The specification, however, only provides the representative species of proteins having the amino acid sequence of SEQ ID NO: 2 and 4. There is no disclosure of any particular structure to function/activity relationship in the disclosed species (see also above 112 second paragraph rejection in reference to the recitations "TFIIA α / β -like factor protein" and "Stoned TFIIA α / β -like factor protein" as it applies to the function of the claimed proteins). The specification also fails to describe additional representative species of these proteins by any identifying structural characteristics or properties other than the characteristics recited in claims, for which no predictability of function is apparent.

The genus of proteins that are claimed is a large variable genus with potentiality of comprising many different proteins. Therefore, many functionally unrelated proteins are encompassed within the scope of these claims. The specification discloses only species of each claimed genus (i.e. having the amino acid sequence SEQ ID NO: 2 and 4) which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicants comments in response to the previous 112 1st paragraph rejection based on a lack of written description are acknowledged, however, contrary to applicants assertion that the newly added claims were drafted in light of the Written description discussed above.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 86-88, 90-99 and 101-107 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated protein having the amino acid sequence of SEQ ID NO: 2 or 4, does not reasonably provide enablement for any "TFIIA α / β -like factor protein" or "Stoned TFIIA α / β -like factor protein" comprising an amino acid sequence of merely having greater than 90% amino acid sequence identity to SEQ ID NOs: 2 or 4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 86-88, 90 and 91 are so broad as to encompass any TFIIA α / β -like factor 90%, 95% or 98% amino acid sequence identity to SEQ ID NOs: 2. Claims 92-96 are

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so broad as to encompass any TFIIA α / β -like factor protein encoded by a polynucleotide comprising a nucleic acid sequence substantially homologous to the coding strand of the gene sequence set forth in SEQ ID NO. 1 and fusion proteins comprising said protein. Claims 97-99 and 101- are so broad as to encompass any Stoned TFIIA α / β -like factor protein encoded by a polynucleotide comprising a nucleic acid sequence substantially homologous to the coding strand of the gene sequence set forth in SEQ ID NO. 1 or 3 and fusion proteins comprising said protein.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of proteins and fusion proteins broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function (see also above 112 second paragraph rejection in reference to the recitations "TFIIA α / β -like factor protein" and "Stoned TFIIA α / β -like factor protein" as it applies to the function of the claimed proteins). However, in this case the disclosure is limited to the teachings of those proteins having the amino acid sequence of SEQ ID NO: 2 and 4

art to screen for multiple substitutions or multiple modifications, as encompassed by the

instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any TFIIA α / β -like factor protein because the specification does **not** establish: (A) regions of the TFIIA α / β -like factor protein structure which may be modified without effecting TFIIA α / β -like factor protein activity; (B) the general tolerance of TFIIA α / β -like factor protein to amino acids to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. Because of this lack of guidance, the extended experimentation that would be required to determine which substitutions would be acceptable to retain the desired activity and the fact that the relationship between the sequence of a polypeptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable (e.g., see Ngo et al. in *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Moras et al. (ed.), Birkhauser, Boston).

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art to arrive at the majority of those polypeptides of the claimed genus having the desired activity.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of amino acid modifications of any TFIIA α / β -like factor protein. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those DNAs having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

It is noted that a similar rejection was made in the previous office action for claims 2, 33, 68, 71, 72, 74-78, 79, 80 and 82-85. In response to this previous rejection applicants cancelled the referred to claims and did not comment on the rejection as it may apply to the newly added claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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Claim 93-96 and 104-107 are rejected under 35 U.S.C. 102(b) as anticipated by Ma et al. (Genes and Development 7(11):2246-2257, Nov 1993).

As stated in the previous office action, Ma et al. teach the cloning and identification of a cDNA clone encoding the largest subunit of TFIIA. The cDNA taught by Ma et al. has a best local similarity score of 66.3 % with nucleotides 3379 to 3663 of SEQ ID NO: 3 and Ma et al. the purification of the TFIIA protein by nickel and TBP chromatography. As a single amino acid constitutes a portion of a TFIIA α / β -like factor protein, Ma et al. teach a fusion protein comprising a portion of a TFIIA α / β -like factor protein and a non-TFIIA α / β -like factor protein sequence.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

All communications should be directed to the receptionist whose telephone number is (703) 305-0196.

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Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

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July 23, 2003